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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/523,044 | 07/14/2005 | Ralph Biemans | B45313 | 7576 |

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| 20462 | 7590 | 10/04/2007 |
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| CORPORATE INTELLECTUAL PROPERTY-US, UW2220 | | |
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| EXAMINER | |
| GRASER, JENNIFER E | |

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| ART UNIT | PAPER NUMBER |
| 1645 | |

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| NOTIFICATION DATE | DELIVERY MODE |
| 10/04/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/523,044

Applicant(s)

BIEMANS ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 14 (only as it pertains to bleb) and 16-18, drawn to a Neisserial bleb preparation.

NOTE: this Group contains a multitude of independent inventions. Applicants are entitled to search of only a single product, e.g., a single bleb preparation. When selecting this Group, Applicants must elect a single strain from:

- a) Derived from a strain with a neisserial L2 LOS immunotype and a lgtB- strain.
- b) Derived from a strain with a neisserial L3 LOS immunotype and a lgtB- strain.
- c) A combination of blebs derived from a neisserial strain with an L2 LOS immunotype and a neisserial strain with an L3 LOS immunotype.

Applicant must **also** elect the capsular polysaccharide genes downregulated or deleted which the preparation contains in claims 4-10. This is *not* a species election, but is a Restriction requirement since these preparations are structurally different and possess different immunogenic properties. A response to this Restriction Requirement which does not specify which downregulated genes the claimed preparation contains will be considered non-responsive.

Group II, claim(s) 11, drawn to a Neisserial bacterial strain. **NOTE:** this Group contains a multitude of independent inventions. Applicants are entitled to search of only a single product, e.g., a single bacterial strain. When selecting this Group, Applicants must elect a single strain from:

- a) A strain with a neisserial L2 LOS immunotype and a lgtB- strain.
- b) A strain with a neisserial L3 LOS immunotype and a lgtB- strain.
- c) A combination of neisserial strains with an L2 LOS immunotype and a neisserial strain with an L3 LOS immunotype.

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Group III, claim(s) 12, 13, 14 (only as it pertains to LOS), 15 and 16-18 and 53, drawn to a LOS preparation. **NOTE:** As outlined in Group I, Applicants must elect a single preparation by reciting which Neisserial strain the LOS is derived, e.g.:

- a) Derived from a strain with a neisserial L2 LOS immunotype and a lgtB- strain.
- b) Derived from a strain with a neisserial L3 LOS immunotype and a lgtB- strain.
- c) A combination of blesbs derived from a neisserial strain with an L2 LOS immunotype and a neisserial starine with an L3 LOS immunotype.

Group IV, claim(s) 19 and 20, drawn to a method of manufacturing a Neisserial bleb preparation. **NOTE:** this Group contains a multitude of independent inventions.

Applicants are entitled to search of only a single method. When selecting this Group, Applicants must elect a single strain which is used in the manufacturing process from:

- a) Derived from a strain with a neisserial L2 LOS immunotype and a lgtB- strain.
- b) Derived from a strain with a neisserial L3 LOS immunotype and a lgtB- strain.
- c) A combination of blesbs derived from a neisserial strain with an L2 LOS immunotype and a neisserial starine with an L3 LOS immunotype.

Group V, claim(s) 21-39 and 55, drawn to a bleb preparation from any Gram-negative bacterial strain comprising an outer-membrane protein conjugated to LOS integrated in the outer-membrane. **NOTE:** this Group contains a multitude of independent inventions. Applicants are entitled to search of only a single product/bleb preparation. When selecting this Group, Applicants must elect a single strain from which the bleb preparation is derived:

- a) H.influenzae
- b) Moraxella catarrhalis
- c) Neisseria

Group VI, claim(s) 40-52 and 54, drawn to a process of producing an intra-bleb conjugated bleb preparation from a Gram-negative bacterial strain comprising an outer membrane protein conjugated to LOS integrated into the outer-membrane.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I is not novel. See Quakyi et al. (Infection and Immunity. Vol. 65, no. 5. 1997, pages 1972-1979). Accordingly, there is a lack of unity between the Groups. The special technical feature of Group I is the bleb preparation which is a product that is biologically, chemically and structurally different than the bacterial strain of Group II. Further, the invention of Group III is biologically, structurally and chemically different than the products of Groups I and II, a LOS preparation. The method of Group IV is not required to make the bleb preparation of Group I. The blebs may be isolated or manufactured in other ways. Lastly, the bleb preparations of Group V are from different sources than those of Group I and are, therefore, biologically, structurally and chemically different products. Accordingly, Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. As outlined in the Groups above, Groups I-V contain a multitude of separate and patentably distinct inventions within each Group that are not species of one another, but are completely different inventions. Applicants must elect a single product for examination in each of these Groups. It is noted that the International Search Authority reported that no international search report was prepared for claims 21-31 and 37-39. The EPO determined that the claims relate to such an extremely large number of possible products, the claims so lack support and the application lacks disclosure, that a meaningful search over the whole of the claimed scope was not possible. The claims still contain an unduly broad scope that even a proper Restriction was difficult to establish. Applicants are required, as outlined above,

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to elect a single product or combo of products since they are only entitled to the search of one product or method per application.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

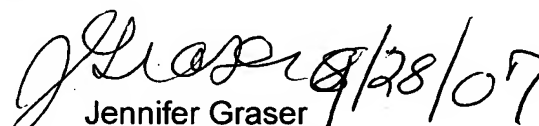
4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner